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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,432	12/06/2001	Shau-Chi Chi	39734-176754	8720

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EXAMINER	
CHEN, STACY BROWN	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,432	CHI, SHAU-CHI	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,10-12,14,16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,8,10-12,14,16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application has been transferred to Examiner Chen of Art Unit 1648. Please direct all further correspondence accordingly. Applicant's amendment and response filed April 17, 2006 is acknowledged and entered. Claims 1, 3-5, 7, 8, 10-12, 14, 16 and 18-22 are pending and under examination.

The rejection of claims 1, 3-5, 7, 8, 10-12, 14, 16 and 18 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, is withdrawn in view of Applicant's amendment filed April 17, 2006.

Claims Summary and Interpretation

The claims are drawn to a vaccine comprising an immunologically effective amount and a sufficient quantity of an inactivated nervous necrosis virus (NNV) for immunizing susceptible fish against viral infection. The inactivated NNV is produced by the following process: NNV is obtained from an immortal cell line, *Epinephelus coioides* (ATCC PTA-859), wherein said NNV is inactivated after being harvested from said immortal cell line. The claims also indicate that the immortal cell line is capable of producing said sufficient quantity of said NNV. The claims have been treated and will continue to be treated as product-by-process claims.

In another embodiment, the vaccine comprising inactivated infectious pancreatic necrosis virus (IPNV), is produced by the same method described above. Also claimed are methods of immunizing susceptible fish.

New claims 19-22 specify that inactivation of the virus is via heat treatment or formalin treatment. Indicating that the inactivation of the virus is performed by these two methods does

not impart a patentably distinguishing feature to the virus because the claims are directed to inactivated viruses. The methods of UV inactivation, heat inactivation and formalin inactivation, though different, result in the same product: an inactivated virus.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(*New Rejection*) Claims 1, 3-5, 7, 8, 10-12, 14, 16 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite, "and a sufficient quantity", which is not supported by the specification. Applicant is invited to point out the particular pages that provide support for the newly added limitation.

Claim Rejections - 35 USC § 102/103

Claims 4, 5, 11, 12, 14, 18, 20 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dorson et al. (Journal of Fish Diseases. 1978; 1: 309-320, "Dorson"), or in the alternative, Dixon et al. (Journal of Fish Diseases. 1983; 6: 399-409, "Dixon"), both of record.

The claims are summarized above. Dorson anticipates an IPNV obtained by a cell culture that has been inactivated by UV. Dorson anticipates administering the inactivated IPNV to trout. See the abstract, "Experimental fish and infection trials" on page 310 and "Ultraviolet inactivation of viruses" on page 311.

Alternatively, Dixon anticipates inactivating IPNV obtained from a cell culture in various ways for vaccine use and administering the inactivated vaccine to fish, see the Materials and Methods section, "*In vivo* tests..." on page 406 and "Immunogenicity tests" on pages 406-407.

Although neither Dorson nor Dixon mention the cell line recited in the claims, there is no distinguishing difference between the instantly claimed inactivated virus obtained by a particular cell line and the inactivated virus obtained by another cell line that is administered by Dorson or Dixon. In the same way, the method by which the claimed viruses are inactivated (UV, heat, formalin) does not result in a materially different virus (structurally and functionally) that distinguishes over those produced by Dorson nor Dixon. Therefore, the Office maintains that the vaccine and method steps of administering the vaccine are anticipated by Dorson or Dixon since there is no distinguishing characteristic imparted from the instant cell culture to the inactivated virus.

Claims 1, 3, 7, 8, 10, 16, 19 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arimoto et al. (Aquaculture. 1996; 143: 15-22, "Arimoto").

Arimoto anticipates inactivating NNV by various methods obtained from a cell culture and administering the inactivated vaccine to fish, see the Materials and Methods and Discussion

sections. Although Arimoto does not mention the cell line recited in the claims, there is no distinguishing difference between the instantly claimed inactivated virus obtained by a particular cell line and the inactivated virus obtained by the cell line of Arimoto for reasons of record.

Response to Arguments

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that it is not the properties of the inactivated NNV or IPNV that distinguish the claimed invention from those described in the prior art cited, but the quantity of the NNV or IPNV that can be propagated from the claimed cell line. Applicant asserts that at the present time, the major problem for producing sufficient vaccine for prevention of NNV or IPNV infection is that the quantity of NNV or IPNV is insufficient to administer the vaccine in a wide-range application, particularly when immersion method for vaccine application is applied. Applicant argues that the instant invention resolves this problem by producing sufficient quantity of NNV or IPNV through GF-1 cell line. In particular, Applicant notes that Dorson's method of virus production results in lower titers than Applicant's method. Applicant also notes that Dixon does not indicate that the IPNV cultivated in BF-2 cells was propagated to the same exponential degree as Applicant's invention.

In response to Applicant's arguments, the interpretation of the claims remains the same as set forth previously. The claimed component actually present in the vaccine is inactivated NNV or IPNV, in an amount sufficient to induce protection of fish against NNV or IPNV challenge. How the inactivated NNV or IPNV is produced does not confer a structural feature to the NNV or IPNV that makes it any more immunogenic than any other inactivated NNV or IPNV. While

Applicant maintains that the inventive concept is the quantity of NNV or IPNV that can be produced from the claimed cell line, the claims are not drawn to a method of producing NNV or IPNV in the claimed cell line. The claims are drawn to the end product of the production method, which is no different than Dorson's virus or Dixon's virus. Both the instantly claimed vaccine and the prior art's vaccine contain an immunologically effective amount of inactivated virus and a sufficient quantity of NNV or IPNV.

In summary, if Applicant's inventive concept is the production of virus in the claimed cell line, then appropriate claims would be, "A method of producing IPNV in *Epinephelus coioides* (ATCC PTA-859)." In that case, the cell line must be considered because it is part of the active steps of the method claims. In the instant case, the claims are product claims. As long as the prior art teaches the same product (regardless of quantity) and method of prior art does not result in a structural and functional difference, then the product claims are anticipated by the prior art's product.

As indicated in the previous Office action, Applicant's 132 declaration, which describes the unexpected result of propagating NNV or IPNV in the deposited cell line derived from a fish that is known to be impervious to NNV or IPNV infection and obtaining twice the titer of the virus propagated in a traditional cell line, fails to persuade. The unexpected infectivity of NNV or IPNV in non-susceptible host cells and the unexpected quantity of virus yielded therefrom characterize unexpected properties of the deposited cell line, not the virus of the vaccine composition or the instant methods of administering the vaccine. Therefore, the rejections are maintained as anticipated by the prior art of record.

Conclusion

No claim is allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 6/22/06

Stacy B. Chen
Primary Examiner
June 22, 2006